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EXAMINER	
NASSER, ROBERT L	

ART UNIT	PAPER NUMBER
3736	8

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/024,506	Applicant(s) DENUZZIO ET AL.	
	Examiner Robert L. Nasser	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,22-40 and 43-65* is/are rejected.

7)☒ Claim(s) *20,21,41 and 42* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4, 6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

This action is being resent to include 2 references that were omitted, Sohrab and Kanner et al.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The subject matter of claims 11 and 35 does not appear to be in the specification. On page 9, in paragraph 31, applicant enumerates several parameters or analytes that may be measured. The claim says measuring both an analyte and a parameter. Paragraph 31 does not seem to support such a claim. Therefore, applicant should amend the claim to include more clearly the subject matter of claims 11 and 35, without introducing any new mater.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48 and 64 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 48 and 64 recite the step of adjusting the potential applied to the active electrode based on the reference electrode. The only disclosure resembling this features is on pages 11 and 12. Page 12 specifically states that the IR drop between the active electrode and the reference electrode is negligible and need not be adjusted for. Therefore, claims 48 and 64 contradict the specification. Clarification is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11 and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Both claims enumerate a list of elements for the parameter and the analyte. The list includes glucose oxidase, glucose deoxyhydrogenase and lactate deoxyhydrogenase. These are neither a patient parameter nor an analyte. Clarification is required.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 9, 10, 13-19, 22-26, 33, 34, 37-40, 43-47, 49, 56, 57, 59-63, and 65 are rejected under 35 U.S.C. 102(e) as being anticipated by Gross et al 6,275,717. Gross et al shows a device for measuring at least one analyte in a patient, including an active electrode 15 that is adapted to pass through the stratum corneum to a depth sufficient to contact body fluid to enable glucose detection electrochemically, and an auxiliary electrode 16 or 17, that partially surrounds the active electrode. Claim 2 is rejected because Gross shows a base 13 integral with auxiliary electrode, where the active electrode extendable beyond the base to a sufficient depth to access the glucose

(see figures 12 and 13). Claim 9 is rejected in that there is a communication device 23 for communicating with an external device. Claim 10 is rejected in that a patient may wear the device of Gross et al. Claim 13 is rejected in that the electrodes 16 or 17 "substantially" surround the active electrode, being as applicant has not provided a definition of the word "substantially." Claim 14 is rejected in that the auxiliary electrode is coupled to the base portion, near where the active electrode extends. Claim 15 is rejected in that an electrical potential is applied to the active electrode (see column 11, lines 35-46). Claim 16 is rejected in that the analyte is electrochemically active. Claim 17 is rejected in that one of the substances measured in detecting glucose is oxygen. Claim 18 is rejected in that the active electrode is platinum-iridium (see column9, line 58). Claim 19 is rejected in that one of the electrodes 16 and 17 is an auxiliary electrode and one is a reference electrode. Both electrodes are equally spaced from active electrode 15. Claims 22 and 23 is rejected in that there is a delivery device integral with the assembly that is adapted to deliver insulin based on the glucose reading. (see 7, lines 52-57). Claim 24 is rejected in that, in addition to the features discussed above, electrode 15 is impregnated with glucose oxidase (see column 10, lines 25-31). Claims 25, 26, 33, 34, 37-40, and 43, 44, are rejected for the reasons given above. Claim 45 is rejected in that Gross et al further teaches the method of placing the electrode against a patient's skin, where the device has an active electrode 15 and an auxiliary electrode 16 or 17, the auxiliary electrode contacting the patient's skin when the active electrode is in the body, applying a potential to the electrodes, and

measuring the current from the electrochemical reaction to measure glucose. Claim 46 is rejected in that the current is an integrated current (see column 12, line 20). Claims 49, 56, 57, 59-63, and 65 are rejected for the reasons given above.

Claims 1, 7, 11-14, 16, 18, 24, 25, 31, 35-38 and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Sohrab. Sohrab shows an active electrode 108 and a reference electrode 12, which surrounds the active electrode. Claim 7 is rejected in that when contacting the skin, reference electrode extends into the stratum corneum. Claim 11 is rejected in that Sohrab discloses the a single array of needles may have a plurality of reagents to measure a plurality of analytes. Therefore, Sohrab teaches detecting the levels of glucose oxidase and lactate deoxyhydrogenase and glucose deoxyhydrogenase. Claim 12 is rejected in that there are a plurality of active electrodes. Claim 13 is rejected in that electrode 112 complete surrounds electrode 108. Claim 14 is rejected in that both electrodes are coupled to the same base. Claim 18 is rejected in that the electrodes are made form the recited materials (see column 8, lines 25-35). Claims 24, 25, 31, 36, 37, and 40 are rejected in that , in addition to the features discussed above, Sohrab has a reagent including glucose oxidase adjacent the active electrode.

Claims 1, 7, 13, 14, 16, 18, 19, 24, 25, 31, 37, 39, and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Watanabe et al. Claim 1 is rejected in that Watanabe et al shows a device having an active electrode 3 and an auxiliary electrode 4, which surrounds the active electrode. The examiner notes that the length of this device is much longer than applicant's. However, the claim only states that the

electrode has a length sufficient to pass through the stratum corneum. The examiner further notes that Watanabe is not inserted through the skin in use, but that is a intended use limitation and Watanabe has a length sufficient to do so. The Watanabe device is 50mm, so it is capable of passing through the stratum corneum. Applicant should further limit the length to define over Watanabe et al. Claim 7 is rejected in that the electrode 4 also has a length sufficient to pass into the stratum corneum when contacting the skin. Claim 13 is rejected in that the electrode 4 surrounds the active electrode 3. Claim 14 is rejected in that electrodes 3 and 4 are both coupled to base 36 (see figure 4) Claim 16 is rejected in that the analyte is electrochemically active. Claim 18 is rejected in that the electrode is made from platinum (see column 3, lines 45-60). Claim 19 is rejected in that there is a reference electrode 63, spaced the same distance from the active electrode as the auxiliary electrode. Claims 24, 25, 31, 37, 39, and 40 are rejected in that, in addition to the features discussed above, Watanabe has the electrode coated with glucose oxidase in layer 17.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 3-5, 27-29, and 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al in view of Kanner et al. The needle of Gross is not

retractable. The examiner notes that Kanner teaches a lancet where the body piercing member is retracted after use automatically via a spring so as to prevent cross contamination and unintentional pricking of the patient. From this teaching, it would have been obvious to modify Gross et al to have the needle extend for use and then retract back inside the device, to limit the device to a single use and prevent cross contamination and injury. The examiner notes that making the retraction and extension automatic or manual does appear to be for a specific purpose and it does not solve a stated problem. Accordingly, it would have been a mere matter of design choice to make the extension and retraction automatic or manual.

Claims 6, 30, and 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al in view of Becker et al. Gross et al does not have an abraded surface on the auxiliary electrode. Becker et al teaches that such a surface is required to decrease the skin resistance and increase measurement accuracy. Hence, it would have been obvious to modify the Gross et al to use such an abraded surface, to increase measurement accuracy.

Claims 8, 32, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al in view of Causey III, et al. Gross et al does not have data storage for storing the glucose levels. Causey III et al provides such storage on a similar device so that the physician can review the trends in the patient's condition at a later time. Therefore, it would have been obvious to modify Gross et al to use such data storage, to allow improved care by the physician.

Claims 8, 32, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sohrab in view of Causey III, et al. Sohrab does not have data storage for storing the glucose levels. Causey III et al provides such storage on a similar device so that the physician can review the trends in the patient's condition at a later time. Therefore, it would have been obvious to modify Sohrab to use such data storage, to allow improved care by the physician.

Claims 9, 22, 23, 33, 43, 44, 45, 46, 47, 49, 54, 57, 58, 60-63, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sohrab in view of Gross et al. With respect to claims 9 and 33, Sohrab does not have a device to communicate with external equipment. Gross et al shows a device for the same purpose as Sohrab that has such a transmitter 23 to send the data to a remote location, e.g. wristwatch display, to allow the user to monitor the levels. From this teaching, it would have been obvious to modify Sohrab to use the transmission system of Gross et al, as it is merely the substitution of one known data reporting means for another. Claims 22, 23, 43, and 44 are rejected in that Sohrab does not have the delivery device. Gross et al teaches that it is known in a glucose monitor to provide a trigger for an insulin pump based off the glucose levels, to provide automated control of glucose levels. Hence, it would have been obvious to modify Sohrab to control such a pump, to provide improved reliability on glucose control. With respect to the method claims, Sohrab teaches all of the claimed features except that it is passive, it only senses the resulting current, it does not bias the electrodes. Gross et al teaches an alternate measuring technique for the same parameters, where a biasing voltage is applied to the electrodes. Hence, it would have

been obvious to modify the above Sohrab to use such a biasing voltage, as it is merely the substitution of one known equivalent measurement technique for another. The remaining method claims are rejected for the reasons given above.

Claims 12, 36, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross et al in view of Sohrab. Gross et al only disclose a single active electrode. Sohrab shows a similar minimally invasive device that has an array of active electrodes. From this teaching, it would have been obvious to modify Gross et al to use a plurality of active electrodes, as it is merely the substitution of one known electrode configuration for another.

Claims 20, 21, 41, and 42 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 20, 21, 41, and 42 define over the art in that none of the art shows a plurality of active electrodes, disposed for sequential use, as claimed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Demarzo shows a similar electrode arrangement to the claimed invention.

Colin shows a similar glucose measuring device with electrode arrangement 21.

Niedrach et al shows an electrode assembly meeting some of the claim features.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0758 for regular communications and (703) 308-0758 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Robert L. Nasser
Primary Examiner
Art Unit 3736

RLN
August 19, 2003

ROBERT L. NASSER
PRIMARY EXAMINER